Food and Drug Administration

FY 2016 Operating Plan Narrative

Overview: The fiscal year (FY) 2016 Final Level for FDA is $4.7 billion for the total program level, which is $240 million above the FY 2015 Final level.[1] Of the total FY 2016 funding received, $2.7 billion is for budget authority (BA) and $2.0 billion is for user fees (UF).

Budget Authority: The FY 2016 budget authority funding provides an additional $132.3 million above the FY 2015 Final Level. This amount provides increases of $104.5 million for Food Safety and for Medical Product Safety including:

- $5.0 million for implementation of the FDA Safety and Innovation Act (FDASIA)
- $8.7 million to support the National Strategy for Combating Antibiotic Resistant Bacteria (CARB)
- $2.4 million for Precision Medicine
- $2.5 million for Orphan Product Grants
- $0.7 million for Sunscreen.

The FY 2016 budget authority funding also provides $5.0 million for Foreign High-Risk Inspections, $6 million for GSA rent increases, and $5 million for FDA to complete a feasibility study to update the Master Plan for White Oak. The FY 2016 budget authority level also includes a reduction of $7.5 million as instructed in the report language.

User Fees: The FY 2016 user fee funding provides an additional $107.8 million above the FY 2015 Final level. This funding will support FDA's implementation of Titles I-IV of the FDA Safety and Innovation Act (FDASIA) and the Family Smoking Prevention and Tobacco Control Act. The bill also appropriates the third party auditor fees, as requested. The FY 2016 appropriation did not include funding for the two major food and feed safety user fee proposals: a Food Import Fee ($103.3 million) and a Food Facility Registration and Inspection Fee ($60.1 million). In addition, the appropriation did not include funding for the proposed Cosmetics, Food Contact Substance Notification, and International Courier Fees, or an increase for the Export Certification fee. Lastly, the Color Certification user fee was reduced by $0.6 million due to the sequester applied to mandatory programs in FY 2016.

Key Initiatives:

Food Safety

The FY 2016 funding level for food safety is $1.3 billion, an increase of $105.2 million above the FY 2015 Final level. The final level includes the $104.5 million increase for food safety identified in the report, reductions categorized as food safety activities ($2.1

[1] The FY 2015 Final Level does not include the one-time increase of $25 million for Ebola Emergency activities.

million), and increases provided for food safety related GSA rent payments that will support base food safety activities ($2.8 million). These resources will allow the FDA to: implement fundamental requirements for domestic food and feed safety; acquire the technical staffing needed to support the law, including the training of new inspectors; provide the appropriate guidance to industry about the changes the law will bring; strengthen the role of the states in helping to ensure the safety of the country's food supply; and build and implement a new import safety system.

FDA Safety and Innovation Act (FDASIA) Implementation
FDA received $5.0 million to support FDASIA Implementation. FDA will implement the Unique Facility Identifier (UFI) mandated under Sections 701 and 702 of FDASIA, which ensures the accuracy and coordination of FDA databases. FDA will also continue with the implementation of a Unique Device Identifier (UDI) system under section 614 of FDASIA. FDA will also implement Section 1136 of FDASIA requiring electronic application submission in 2016 for biological products not covered by user fees.

Combating Antibiotic Resistant Bacteria
FDA received an increase of $8.7 million, for a total of $39.6 million in budget authority, to support the National Strategy for Combating Antibiotic Resistant Bacteria (CARB). FDA will evaluate new antibacterial drugs for patient treatments, streamline clinical trials, develop better vaccines for antibiotic resistant organisms, and strengthen capacities to detect antibiotic resistance.

Foreign High-Risk Inspections
FDA received a $5.0 million increase to support foreign high-risk inspections. This funding will allow FDA to continue efforts to develop and utilize a targeted, risk-based, and efficient inspection model that incorporates commercially available information on high-risk establishments for onsite verifications.

Precision Medicine
FDA received $2.4 million to support precision medicine. Precision medicine is guided by comparing an individual's profile to a massive data network that includes information about other patients as well as data from research studies. This funding will permit FDA to support the development of promising new therapeutics that are needed for integrating genetic information into device development.

Orphan Product Grants
FDA received an increase of $2.5 million, for a total of $16.5 million, to support Orphan Product Grants. This funding will promote and advance the development of innovative products that demonstrate promise for the prevention, diagnosis, and/or treatment of rare diseases or conditions.

Sunscreen
FDA received $0.7 million to support the evaluation of over the counter (OTC) sunscreen products, including activities related to reviewing the validity and outcome of

new pharmacology and toxicology data, conducting searches of public literature and data, and writing summaries of relevant pharmacology and toxicology data.

White Oak Feasibility Study
FDA received $5 million for a feasibility study to update and issue a revised Master Plan for FDA's expanded workforce as a result of recently enacted responsibilities and resources. The feasibility study will provide the options necessary to assess the most cost effective way to house FDA's current and projected personnel.

Office of Cosmetics and Colors
FDA will spend not less than $11.7 million on cosmetics activities. Within that amount, CFSAN will spend not less than $8.1 million, including activities within the Office of Cosmetics and Colors as well as other offices supporting cosmetics activities.

Transfers: FDA was instructed to transfer $1.5 million from FDA Headquarters to the HHS Office of Inspector General to support oversight of FDA's expanded authorities.